UNITED STATES DISTRICT COURT
DISTRICT OF NEW MEXICO

UNITED STATES OF AMERICA,

Plaintiff,

v. Case No. 1:22-CV-830

WILLIAM C. GARDNER, DDS

Defendant.

COMPLAINT FOR VIOLATION OF THE CONTROLLED SUBSTANCES ACT AND THE FALSE CLAIMS ACT

Plaintiff, the United States of America, brings this action for civil penalties against Defendant William C. Gardner, DDS for violation of the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act, 21 U.S.C. §§ 801-971, and the regulations promulgated thereunder ("the CSA") and for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"). In support of its claims, the United States of America alleges upon information and belief as follows:

JURISIDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 21 U.S.C. §§ 842(c) and 28 U.S.C. §§ 1331, 1345, and 1355.

2. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a). Jurisdiction is proper over Defendant because Defendant maintains his dental office in this Court's jurisdiction, and the acts in violation of the CSA and FCA occurred within this District

3. Venue is proper in the District of New Mexico pursuant to 28 U.S.C. §§ 1391, 1395(a) in that the acts and omissions described and giving rise to the claims asserted here occurred in the District of New Mexico.

PARTIES

4. Plaintiff in this action is the United States of America, suing on behalf of the United States Department of Justice, Drug Enforcement Administration ("DEA"), the United States Department of Health & Human Services ("HHS") and its operating division, the Centers for Medicare & Medicaid Services ("CMS"), the Department of Defense, including its component, Tricare.

5. Defendant William C. Gardner, DDS practices dentistry in the State of New Mexico.

LEGAL AND REGULATORY FRAMEWORK

Controlled Substances Act

6. The CSA governs persons that manufacture, distribute, and dispense controlled substances.

7. The CSA prohibits a person "who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title." 21 U.S.C. § 842(a)(1).

8. Part C refers to the registration of manufacturers, distributors, and dispensers of controlled substances. 21 U.S.C. § 821 *et seq*.

9. The term "dispense" means to deliver a controlled substance to an ultimate user . . . , including the prescribing . . . of a controlled substance. . . ." 21 U.S.C. § 802 (10).

10. Section 829 provides:

> (a) Schedule II substances
> Except when dispensed directly by a practitioner, . . . no controlled substance in schedule II . . . may be dispensed without the written prescription of a practitioner, except that in emergency situations, . . . such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act. . . .
> (b) Schedule III and IV substances
> Except when dispensed directly by a practitioner, . . . no controlled substance in schedule III or IV . . . may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. . . .

> (c) Schedule V substances
> No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

11. A "'practitioner' means a . . . dentist . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . ., to distribute, dispense, . . . a controlled substance in the course of professional practice . . . ." 21 U.S.C. § 802(21).

12. The CSA regulations provide in relevant part:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose *by an individual practitioner acting in the usual course of his professional practice*. . . . An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
>
> * * *

21 C.F.R. § 1306.04 (emphasis added).

13. If the prescription was unlawful, "it follows that section 829 has not been complied with." *United States v. Green*, 511 F.2d 1062, 1070 (7th Cir. 1975).

14. The CSA makes it unlawful for a person who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of 21 U.S.C. § 829; 21 U.S.C. § 842(a)(1).

15. The CSA also establishes penalties:

> (c) Penalties
> (1)(A) Except as provided in subparagraph (B), (C), or (D) of this paragraph and paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. . . .
>
> * * *

21 U.S.C. § 842.

16. The penalties are regularly adjusted, and the maximum penalty is determined at the time it is assessed. 28 C.F.R. § 85.5 (effective Dec. 13, 2021). At the time of this filing, the maximum penalty assessed after May 9, 2022, for violation of 21 U.S.C. § 842(a)(1), is $ 72,683. 87 FR 27513-01.

17. "Each violation may result in a civil penalty" up to the statutory cap. *United States v. Appalachian Reg'l Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1192 (E.D. Ky. 2017).

18. The civil remedies in the CSA help combat the diversion of controlled substances that are commonly sold and used illegally.

False Claims Act

19. The FCA provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, . . .
> * * *

is liable to the United States for statutory damages and penalties. 31 U.S.C. § 3729(a)(l)(A)-(B).

20. The FCA defines "knowing" and "knowingly" as having "actual knowledge of the information;" acting "in deliberate ignorance of the truth or falsity of the information;" or acting "in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1).

21. "Knowing" and "knowingly" does not require proof of specific intent to defraud. *Id.*

22. The FCA provides that a person is liable to the United States for three times the damages, which the Government sustains because of the act of that person, plus civil penalties. 31 U.S.C. § 3729(a)(l).

23. The civil penalty for violations occurring between September 28, 1999, and November 2, 2015, is from $5,500 to $11,000. 28 C.F.R. § 85.3 and 64 Fed. Reg. 47099, *47103

(1999).

24. For civil penalties assessed after May 9, 2022, whose associated violations occurred after November 2, 2015, the penalty range is from $12,537 to $25,076. *See* Civil Monetary Penalties Inflation Adjustments for 2022, 87 FR 27513-01.

25. A person violating the FCA is also "liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages." 31 U.S.C. § 3729(a)(3).

The Medicare Program

26. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq*., establishes the Health Insurance for the Aged and Disabled Program, commonly referred to as "Medicare."

27. Medicare pays for health care services that are medically indicated and necessary for the health of the patient, and are provided, ordered, supplied, or prescribed by or incident to the care of an authorized provider. 42 U.S.C. § 1395k, 1395l(a), 1395y(a)(1)(A); 42 C.F.R. 411.15(k).

28. Medicare is comprised of four parts. Part D of Medicare was enacted as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries.

29. All persons enrolled in Medicare Part A or Medicare Part B are eligible to enroll in a prescription drug plan under Part D.

30. HHS, through CMS, contracts with private companies ("Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

31. Generally, a medical provider, such as Defendant, writes a prescription for a patient who is a Medicare beneficiary, and that patient takes the prescription to the pharmacy to be filled.

When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor. The pharmacy receives reimbursement from the sponsor for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

32. Payments to a Part D sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

33. The payments made by CMS to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

34. All prescribers of Part D drugs must enroll in Medicare. This includes dentists.

35. A qualified health care professional must complete and sign a Medicare Enrollment Application and includes a "Certification Statement" setting forth standards that must be met for initial and continuous enrollment in the Medicare program to order and certify items and services

for Medicare beneficiaries or prescribe Part D drugs. The enrollee agrees to adhere to the requirements listed, including:

a. The enrollee has read and understood the penalties for submitting false information to Medicare.

b. The enrollee understands that any deliberate omission, misrepresentation, or falsification of any information contained in any communication supplying information to Medicare may be punished by criminal, civil and/or administrative penalties including, but not limited to the imposition of fines, civil damages and/or imprisonment.

c. The enrollee agrees to abide by the Medicare laws, regulations, and program instructions.

d. The enrollee understands that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions.

e. The enrollee will not knowingly order and/or certify an item and/or service or prescribe Part D drugs that allows a false or fraudulent claim to be presented for payment by Medicare.

The Medicaid Program

36. Title XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396-1296v, establishes Medicaid, a jointly funded federal-state program designed to finance medical care for indigent Americans.

37. New Mexico participates in Medicaid program pursuant to N.M.S.A. 1978 § 27-2-12, Medical Assistance Programs.

38. The State funds dental services under the Public Assistance Act, NMSA §§ 27-2-1 through 27-2-47 ("PAA"). Pursuant to the PAA, the New Mexico Human Services Department ("HSD") and its Medical Assistance Division ("MAD") administer the New Mexico Medicaid program in accordance with the New Mexico "State Plan Under Title XIX of the Social Security Act Medical Assistance Program," the requirements of Titles XI and XIX of the Social Security Act, and all applicable Federal regulations.

39. All services must be furnished within the limits of Medicaid benefits, the scope and practice of the provider as defined by state law, and applicable federal, state, and local laws and regulations. NMAC 8.301.2.9(B).

40. A New Mexico Medicaid provider is any individual, corporation, partnership, or other association who provides treatment, goods, and services to beneficiaries of, and bills such items to, the New Mexico Medicaid Program. NMSA 1978 § 30-44-2K, M, and N.

41. A dentist or dental office must sign a Provider Participation Agreement ("PPA") with HSD/MAD, as an individual or organization that will directly receive Medicaid funds ("Form MAD 335") or as an individual associated with an organization that will receive the funds ("Form MAD 312").

42. In the PPA, Defendant agreed to comply with all federal, state, and local laws, rules, regulations, and policies, including but not limited to those applicable to Medicaid, *see, e.g.,* Ex. 5, Article 1, § 1.1; to comply with all applicable State licensure requirements, *id*. § 1.6; to furnish and update complete information on the provider's licensing certification, *id*. § 1.8; to comply with all federal, state, and local laws and regulations regarding licensure, *id.* § 1.9; to verify the identity of the eligible recipient on all occasions prior to rendering services, *id*. § 1.12; and for the PPA to be governed by laws of the State, *id*. Article XVI.

43. Defendant signed the Professional Provider Agreement stating that he understood that payment of claims will be from federal and state funds and that falsification or concealment of a material fact may be prosecuted under federal and state law.

44. Once enrolled as a New Mexico Medicaid provider, providers, including Defendant, receive a packet of information, including Medicaid program policies, billing instructions, utilization review instructions, and other pertinent material from the State of New Mexico's Medicaid fiscal agent. Providers are responsible for ensuring that they have received these materials and for updating them as new materials are received from the State of New Mexico HSD, MAD.

TRICARE

45. TRICARE (formerly CHAMPUS) is a federally funded medical benefit program established by statute. 10 U.S.C. §§ 1071-1110.

46. TRICARE provides health care benefits, including prescription drug coverage, to eligible beneficiaries, which include, among others, active-duty service members, retired service members, and their dependents.

47. TRICARE is funded by the United States. 10 U.S.C. § § 1071 *et seq*.

48. TRICARE is administered through the Department of Defense.

FACTS GIVING RISE TO THIS COMPLAINT

49. Defendant held a New Mexico dental license (License No. DD 1867) that was revoked effective January 1, 2020.

50. Defendant was registered with the United States Department of Justice, Drug Enforcement Administration ("DEA") as a practitioner to handle controlled substances under DEA BG9826427, which was set to expire September 30, 2021.

51. Defendant also held a New Mexico controlled substances license (License No.

CS00019456) that expired by its terms on September 30, 2020.

52. On September 12, 2019, Defendant was indicted on 9 counts of making false application, claim, or proof of loss in violation of N.M.S.A. 1978 § 59A-16-23.

53. The New Mexico Board of Dental Health Care (the "Board") found that there was substantial evidence that Defendant submitted false claim forms to Delta Dental for the purpose of obtaining payment for an unnecessary dental procedure, that he falsified an x-ray, and that he failed to cooperate with the Board's investigation of the allegations. Consequently, the Board revoked Defendant's license to practice dentistry in the State of New Mexico effective January 1, 2020. *In the matter of William Garner, DDS*, before the New Mexico Board of Dental Health Care, No. 18-61-COM, Decision and Order dated November 26, 2019.

54. Defendant sought a stay of the revocation on December 19, 2019, which was granted. The Court subsequently lifted the stay and ordered "the Board may enforce its Decision and Order on July 17, 2020." *See*, *Gardner v. New Mexico Board of Dental Health Care*, No. D-101-cv-2019-2207 (Order entered 7/7/2020).

55. The Board of Dental Health Care separately issued a Decision and Default Order confirming the revocation of Defendant's dental license on December 12, 2020. *In the matter of William Gardner, DDS*, No. D-18-32-COM (Decision and Default Order dated December 12, 2020). The Decision and Default Order specifically ordered "that this revocation of Respondent's license does not affect, modify or change the earlier revocation of Respondent's license on July 17, 2020." *Id.*

56. The DEA found that from July 17, 2020, through February 17, 2021, Defendant wrote 92 prescriptions for controlled substances, two of which were refilled, including the following:

- 73 prescriptions for Vicodin (hydrocodone-acetaminophen, a Schedule II controlled substance) 10-325 mg, totaling 1,324 dosage units;
- 3 prescriptions for Vicodin 7.5-325 mg, totaling 70 dosage units;
- 1 prescription for Vicodin 7.5-300 mg, totaling 25 dosage units;
- 1 prescription for Vicodin 7.5-750 mg, totaling 30 dosage units;
- 1 prescription for Demerol (pethidine, a Schedule II controlled substance) 50 mg, totaling 25 dosage units;
- 1 prescription for hydrocodone--chlorpheniramine extended-release suspension (a Schedule II controlled substance), totaling 30 dosage units;
- 1 prescription for Percocet (oxycodone-acetaminophen, a Schedule II controlled substance) 10-325 mg, totaling 40 dosage units;
- 1 prescription for Percocet 7.5-325 mg, totaling 20 dosage units;
- 1 prescription for Tylenol #3 (codeine-acetaminophen, a Schedule III controlled substance), totaling 20 dosage units;
- 3 prescriptions for diazepam 10 mg (a Schedule IV controlled substance), totaling 35 dosage units;
- 3 prescriptions for diazepam 5 mg, totaling 50 dosage units; and
- 5 prescriptions for tramadol 50 mg (a Schedule IV controlled substance), totaling 212 dosage units.

57. On January 29, 2021, DEA investigators visited Defendant's office and observed Defendant treating a patient.

58. When DEA investigators inquired about the status of Defendant's state license, Defendant falsely claimed that his license was active.

59. The DEA investigators responded by informing Defendant that issuing prescriptions without the required licenses violated both New Mexico and federal law and would constitute illegal distribution of controlled substances.

60. Defendant responded that he understood what DEA investigators had explained.

61. On February 4, 2021, in an ongoing state criminal matter, the New Mexico Second Judicial District Court entered an order that Defendant shall not practice dentistry without a license from the Board. *See*, *State of New Mexico v. William Gardner*, D-202-CR-2019-002948, Stipulated Order Amending Conditions of Release entered on February 4, 2021.

62. Defendant continued to issue prescriptions, including prescriptions for controlled substances, despite being told by both federal and New Mexico authorities that his continued prescribing of controlled substances was unlawful. Upon information and belief, Defendant continues to practice dentistry without a license.

63. On May 11, 2021, the DEA Acting Administrator issued an Order to Show Cause and Immediate Suspension of Dr. Gardner's DEA Registration on the ground that his continued registration constituted an imminent danger to the public safety.

64. On May 13, 2021, an Immediate Suspension Order was served to Dr. Gardner. Dr. Gardner requested a hearing and claimed that the revocation of his license was not yet "effective."

65. The Administrative Law Judge granted the DEA's motion for summary disposition because Dr. Gardner lacked State authority to handle controlled substances.

66. Neither party filed exceptions to the ALJ's decision, and the ALJ transmitted the record for final Agency action.

67. The DEA Administrator revoked Dr. Gardner's DEA Certificate of Registration and denied any pending application to renew or modify his registration, effective November 1, 2021.

68. After his license was revoked, Dr. Gardner wrote prescriptions that were paid for by Medicare Part D. Attached as **Exhibit A** are the prescriptions written by Dr. Gardner that were paid for by Medicare Part D.

69. The Medicare Part D program suffered a loss of about $35.30 for these prescriptions.

70. After his license was revoked, Dr. Gardner wrote prescriptions that were paid for by Medicaid. Attached as **Exhibit B** are the prescriptions written by Dr. Gardner that were paid for by Medicaid.

71. The Medicaid program suffered a loss of $87.82 for these prescriptions.

72. After his license was revoked, Dr. Gardner wrote prescriptions that were paid for by Tricare. Attached as **Exhibit C** are the prescriptions written by Dr. Gardner that were paid for by Tricare.

73. The Tricare program suffered a loss of $27.42 for these prescriptions.

FIRST CLAIM FOR RELIEF
Controlled Substances Act

74. The United States re-alleges and incorporates by reference the foregoing allegations.

75. By virtue of the acts described above, Defendant violated 21 U.S.C. § 829 (a)(1) and 21 C.F.R. § 1306.04.

76. Defendant is liable to the United States for a civil penalty for each occasion on which the defendant committed a violation.

SECOND CLAIM FOR RELIEF
False Claims Act Violations

77. The United States re-alleges and incorporates by reference the foregoing allegations.

78. It is unlawful to practice dentistry in New Mexico without a license and without complying with the Dental Health Care Act.

79. The practice of dentistry includes "the prescription or administration of any drug [or] medicine." N.M.S.A. 1978 § 61-5A-4.

80. As set forth more fully above, Defendant knowingly practiced dentistry without a license, including writing fraudulent prescriptions for patients.

81. Defendant knew the prescriptions he wrote were false or fraudulent because he was writing them without a license to do so.

82. Defendant's patients had the prescriptions filled at pharmacies.

83. The pharmacies that filled the prescriptions billed Medicare, Medicaid, and Tricare for the prescriptions.

84. By writing the unlawful prescriptions, Defendant caused pharmacies to submit false claims seeking reimbursement from Medicare, Medicaid, and Tricare for these unlawful prescriptions.

85. By writing the unlawful prescriptions, Defendant knowingly made a false record or statement, thereby causing pharmacies to submit a false or fraudulent claim.

86. Medicare, Medicaid, and Tricare paid for the prescriptions set forth in Exhibit A, B, C, respectively.

87. Medicare, Medicaid, and Tricare would not have paid for the prescription medication if they had known that Defendant did not have a license to practice dentistry, which includes writing prescriptions.

88. Defendant violated the FCA by writing the unlawful prescriptions which caused the pharmacies to submit false or fraudulent claims for payment to Medicare, Medicaid, and Tricare when he illegally wrote prescriptions for patients who were also beneficiaries of Medicare, Medicaid, or Tricare.

PRAYER FOR RELIEF

WHEREFORE, the United States demands judgment against Defendant as follows:

A. Three times the damages which the Government sustained because of Dr. Gardner's violation of the FCA;

B. Civil penalties for each violation of the FCA;

C. A civil penalty for each of the prescriptions for a controlled substances dispensed in violation of the CSA; and

D. For such other relief at law and at equity as the Court deems just and reasonable.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the United States demands a trial by jury in this action of all issues so triable.

Respectfully submitted,

ALEXANDER M.M. UBALLEZ
United States Attorney
District of New Mexico

/s/ Ruth F. Keegan
RUTH F. KEEGAN
Assistant United States Attorneys
201 Third Street, NW, Suite 900
Albuquerque, NM 87102
(505) 346-7274
(505) 346-7205 Facsimile
ruth.f.keegan@usdoj.gov